

## **REMARKS**

Claims 11-16, 51, and 57-75 remain in the application for further prosecution. In the amendments, the phrase “without contacting said metal surface with non-titanium particles” has been removed from claims 11, 51, and 63. Claims 57, 63, and 68 have been amended for consistency with the other claims by including the word “substantially”.

This amendment is being submitted pursuant to a telephone interview November 25, 2003 with Examiner Prebilic regarding the rejections under 35 U.S.C. § 112. The Applicant’s attorneys appreciate the Examiner’s reconsideration of the issues and for his advice.

### **I. Rejections Under 35 U.S.C. § 112**

Claims 11-16, 51, and 60-75 have been rejected under 35 U.S.C. § 112 as not conveying to one skilled in the art that the inventor had possession of the claimed invention. More specifically, the Examiner objected to the use of the word “substantially.” The Examiner contended that one skilled in the art would not be able to determine what degree of roughness or amount of native oxide removed would be within the scope of the claims. The Applicants consider the word “substantially” appropriate with respect to the present invention, as the photomicrographs make clear. At 2000X magnification, it is clear that the surface is not perfectly uniform, but it can be seen to be substantially uniform. That is, the claims are as precise as the subject matter permits. See *Andrew Corporation vs. Gabriel Electronics Inc.*, 6 U.S. P. Q. 2d, 2010 (1988). One skilled in the art would understand the meaning of “substantially uniform” in view of the description of the etched surfaces in the specification and the photographs of the surfaces. The Applicants also note that claims containing the words “substantially” have been allowed in related patents, e.g. U.S. 5,876,453; U.S. 6,491,723; and U.S. 6,652,765. Thus, withdrawing the rejection under 35 U.S.C. § 112 would be consistent with previous practice. The Applicants understand, from the teleconference of November 25, that the Examiner intends to withdraw the rejection.

The Examiner also objected to the new phrase “without contacting said metal with non-titanium particles” added in the last amendment as indefinite. The Examiner is correct in stating that this phrase could be interpreted in two ways; it was the Applicant’s intention to include both possibilities within the scope of the claims. The purpose of adding the phrase was to exclude

contacting the surface (e.g. grit-blasting) with particles that were not titanium, such as the aluminum oxide taught by the previously cited Schulte reference. As discussed with the Examiner, since Schulte is no longer cited, removing the phrase is believed to be appropriate. The Applicants understand that the Examiner intends to withdraw the rejection, if the limitation is removed.

## **II. Rejections Based on Haruyuki and Krueger**

Claims 11-16, and 57-59 have been rejected under 35 U.S.C. § 103(a) as being obvious over Haruyuki et al (“Haruyuki”) in view of Krueger. Haruyuki was cited for a titanium implant surface with recesses having depths of 0.5 to 5 microns. Krueger was cited for the use of threads on dental implants.

Haruyuki applies a two step process to titanium implants. First, he pre-treats with a solution of hydrofluoric acid to etch the surface, then follows with a second treatment with a mixture of hydrofluoric acid and hydrogen peroxide, “to smooth the sharp edges and sharp spines ... produced during the pretreatment.” (translation; page 4, right column lines 7-9) This is clear from the Haruyuki photographs reproduced in Exhibit I of the Gubbi declaration filed June 30, 2003. See Figure 2 showing only HF treatment (4% HF, 1 minute) and Figure 4 showing both treatments (4% HF, 1 minute; 4% HF & 8% H<sub>2</sub>O<sub>2</sub>, 15 seconds). In the Applicants’ process, a minimum amount of titanium metal is removed after the native oxide has been consumed. See Gubbi Exhibit A, Stage 1. It is evident that the titanium surface is relatively smooth even at 2000X magnification, compared to the roughness created by the second-stage etching. See Gubbi Exhibit A, Stage 11. In the Applicants’ process, as it is claimed in the present application, roughening occurs in the second step in which the native oxide-free surface is roughened by an acid treatment.

The Examiner has concluded that the treatments used by Haruyuki produce cone-shaped elements and that the surface irregularities are inherently the same as the Applicant surface. However, the Applicant’s urge the Examiner to reconsider this position as Haruyuki is non-enabling to one skilled in the art. As the Examiner is aware, the Applicants have spent substantial time and effort testing the procedure set forth in Haruyuki. The Applicants have found that Haruyuki’s surface could not be repeated. This should be clear from a review of the

results provided by Dr. Gubbi in Exhibit B, which repeats Haruyuki's examples. Comparative Example 2, of Gubbi's results does not look like the corresponding photograph of the Haruyuki patent (Exhibit 1 Fig. 2) even though both were exposed to 4% HF for 1 minute. The difference between the surface shown in the Haruyuki photographs (Exhibit 1) and the results obtained by Gubbi using the same procedures cannot be explained. Note also the remaining photos in Exhibit B of the results obtained by Gubbi (Exhibit B) using Haruyuki's procedures. Examples 1-5 appear much the same as Comparative Example 2 and do not appear to show a surface corresponding to the Applicant's surface as shown in Exhibit A Stage 11, or to the Haruyuki photos of Exhibit 1, even though the magnification is the same. Experimental Examples 1 and 2, which used only H<sub>2</sub>O<sub>2</sub> as a second treatment are somewhat different, but they also do not show to the characteristic appearance of the Applicant's inventive surface (Exhibit A, Stage 11). In short, following Haruyuki's process did not lead to the results suggested by Haruyuki. More importantly, following Haruyuki's process did not lead to the Applicant's claimed surface.

As the Gubbi Declaration shows, the surface irregularities of Haruyuki are not inherently the same as those of the Applicants. It is clear that neither the first step, nor the second step, of Haruyuki's process produces the same results as the Applicants' process. If one skilled in the art, as Dr. Gubbi certainly is, cannot produce the results shown in the Haruyuki patent, it cannot be said to be enabling. If so, then Haruyuki should not be relied on by the Examiner.

A prior art reference must teach the skilled artisan how to make the invention without undue experimentation. *In re Wright*, 999 F.2d, 557 (Fed. Cir 1996). Also, see MPEP 2121. The Applicants have tested Haruyuki and found the surface disclosed in Haruyuki cannot be replicated. That being the case, Haruyuki cannot be used to reject the claims because it is not enabling with respect to the surface it discloses. The enablement issue is not -- can the skilled artisan understand what the surface discloses? Rather, the enablement issue is - - could the skilled artisan make Haruyuki's surface with the information provided in Haruyuki. The answer appears to be "NO."

Kreuger is no longer cited for his process and his resulting surface, but only for the use of threads. It has previously been pointed out that Kreuger's process was not sufficiently described to be enabling. Dr. Gubbi, in response to the Examiner's suggestion in his March 26, 2003 Office Action, carried out tests but could not etch titanium surfaces to the extent recommended

by Kreuger. See Exhibits C & D. Furthermore, it is significant that while Kreuger shows a threaded implant, he teaches to etch the entire implant to “**as great extent as reasonably possible.**” (Column 3, lines 52-53) or “at least to the extent that the etch ratio... is at least 2”. Column 4, lines 4-5. Combining the non-enabling Krueger reference with the non-enabling Haruyuki reference could not enable one skilled in the art to make the Applicant’s invention. Even if the references were enabling, they should not be combined since Kreuger teaches away from Haruyuki. Kreuger teaches etching the entire surface of an implant. He provided no details of his method, but etching in a single step appears to be implied. However, Haruyuki teaches a two-step process in which the second step is specifically intended to smooth the surface that was roughed by the first step. Translation; page 4, right column lines 7-9. Thus, even if these two references were enabling, the skilled artisan would not combine these two references and achieve the claimed implants set forth in claims 11-16, and 57-59. This is especially true for claims in which the roughening of the second step is provided by a mixture sulfuric and hydrochloric acids, which is **not** disclosed in either reference. See claims 15, 57, 59, 61, 67, and 72.

### **III. Rejections Based on Haruyuki in view of Niznick**

Claims 51 and 60-75 have been rejected under 35 U.S.C. 103(a), based on Haruyuki combined with Niznick. Niznick was specifically cited for teaching that different regions of an implant may have different degrees of roughness and for a self-tapping feature. Yet, as discussed below, Niznick’s teaching of where, and to what degree, to roughen the implant is **substantially** different from the invention of claims 51 and 60-75.

Haruyuki has already been discussed above. In summary, Haruyuki is considered non-enabling and, therefore, insufficient to make the Applicant’s inventive surface obvious. Thus, the rejection should be removed for this reason alone.

But, even if Haruyuki were enabling and could be combined with Niznick, the combination still fails as Niznick is contrary to the teachings of Haruyuki. Niznick teaches the implant’s lower end at the self-tapping region 8 (FIG. 1) or 21 (FIG. 2) should be roughened up to a peak-to-valley height of 20 microns. Column 5, lines 16-20; Column 7, lines 11-15 & 41-45. Niznick considers these surface “smooth” compared to the middle section, which is rougher with a peak-to-valley height of **at least** 25 microns. In fact, these extremely rough surfaces at the

three distinct locations on the implant is Niznick's invention as set forth in Niznick's claim 1. As such, it appears that Niznick considered even "smooth" surfaces to be much rougher than the Applicant's roughened surface. Consequently, the skilled artisan would never combine the teachings of Niznick with those of Haruyuki to produce Applicant's claimed implant surface as the teachings by Niznick are directed to producing an implant surface much rougher than Haruyuki or the Applicants.

Furthermore, claim 57 requires a smooth head portion and a threaded portion with a roughened region extending to the lowermost end, wherein the roughened region has a substantially uniform array of irregularities having peak-to-valley heights no greater than 10 microns. This configuration is not disclosed in Niznick, and Niznick actually teaches away from it with his three-part surface roughness.

Claim 63 requires that the head portion have a smooth machined surface, and a self-tapping region adjacent to the lowermost end. A threaded portion is located between the head portion and the lowermost end and has a roughened region extending to the lowermost end, wherein the roughened region has a substantially uniform array of irregularities having peak-to-valley heights no greater than 10 microns. The acid-etched surface is located within the self-tapping region. This configuration is not disclosed by Niznick, and Niznick actually teaches away from it with his three-part surface roughness.

Claim 68 requires cylindrical and tapered sections and a self-tapping region within the tapered section. A threaded portion is located between the head portion and the lowermost end. A roughened region extends from the lowermost end and into the cylindrical section, wherein the roughened region has a substantially uniform array of irregularities having peak-to-valley heights no greater than 10 microns. Niznick not only fails to disclose this configuration, but most definitely teaches against it.

In short, in addition to the fact that (i) Haruyuki is not enabling and (ii) Niznick clearly teaches away from Haruyuki, the proposed combination of the Haruyuki and Niznick fails to teach all of the elements of claims 51 and 60-75.

#### IV. Product by Process Claims

*The Examiner* has cited MPEP § 2113, which discusses product-by-process claims and emphasizes that the resulting structure is compared with the art. In the present case, the process produces a surface that is distinguishable from the prior art. From the prior art references and the tests conducted by Dr. Gubbi, it can be seen that different processes may create different surfaces. In particular, the surface produced by Gubbi using Haruyuki's methods is not the same as the surface appears in the Haruyuki patent. One can conclude that the Haruyuki patent is not enabling, that is, it does not make it possible for the skilled worker to duplicate Haruyuki's surface. Hence, the Applicants respectfully request that the Examiner not ignore the process steps required by the pending claims.


#### V. Conclusion

If the Examiner considers that further amendment is needed, he is invited to contact the Applicant's attorney at the telephone number provided below.

The Commissioner is hereby authorized to charge deposit Account No. 10-0447 (47168-00035USC1) for any fees inadvertently omitted which may be necessary now or during the pendency of this application, except for the issue fee.

Respectfully submitted,

11/23/04  
Date

  
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